

Message

From: Barbero, Robbie [Roberto_J_Barbero@ostp.eop.gov]
Sent: 2/26/2016 9:42:10 PM
To: Kough, John [Kough.John@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]
Subject: RE: wolbachia and zika virus

Sure. I'll call you at that number. Thanks!

From: Kough, John [mailto:Kough.John@epa.gov]
Sent: Friday, February 26, 2016 4:42 PM
To: Barbero, Robbie; Wozniak, Chris
Subject: RE: wolbachia and zika virus

Surely. Monday at 9:30 works for me. Should Chris and I expect to be called then?

John Kough
703-308-8267

Sent from my Windows Phone

From: Barbero, Robbie
Sent: 2/26/2016 4:32 PM
To: Kough, John; Wozniak, Chris
Subject: RE: wolbachia and zika virus

Thanks, John.

Any chance you could chat on Monday morning at 9:30? Would love to get a few more details from you on the Kentucky project and on the WHO meeting.

From: Kough, John [mailto:Kough.John@epa.gov]
Sent: Friday, February 26, 2016 4:09 PM
To: Barbero, Robbie; Wozniak, Chris
Subject: RE: wolbachia and zika virus

Robbie,
Just to give you a quick reply and be ready for more questions on Monday. We have in place an experimental use permit for looking at the efficacy of the U of Kentucky Wolbachia against Ae. aegyptii in 3 states. This is basically similar to a sterile male release technology using the Wolbachia infected males. I attended a WHO meeting with Eliminate Dengue last May in Geneva where we discussed both their project and more directly population control of mosquitoes using Wolbachia. I pointed out the issues Chris mentioned about jurisdiction. I believe we have had a brief communication since then but not a formal meeting.
Look forward to your further questions on Monday.
John Kough

Sent from my Windows Phone

From: Barbero, Robbie
Sent: 2/26/2016 3:37 PM

To: Wozniak, Chris
Cc: Kough, John
Subject: RE: wolbachia and zika virus

Thank you so much, Chris, for the quick response. I asked a similar question of Laura Pillsbury in the Commissioner's office, so we'll see if she's able to find out the same thing.

John — I'll follow up next week if I have additional questions.

From: Wozniak, Chris [mailto:wozniak.chris@epa.gov]
Sent: Friday, February 26, 2016 3:35 PM
To: Barbero, Robbie
Cc: Kough, John
Subject: RE: wolbachia and zika virus

Hi Robbie,

As is often the case, it is complicated. We feel we clearly have jurisdiction over the Wolbachia as used by the University of Kentucky, handling it as a microbial pest control agent under FIFRA. The Eliminate Dengue approach is a little different in that the target is the ability to transfer an infectious agent (i.e., dengue virus). In a recent conversation with an attorney at FDA-CVM, the thought was that this one is still somewhat up in the air, although more likely than not it would be handled as an Investigative New Animal Drug (INAD) by CVM. You'll note that Oxitec never claims to manage / control the degree of disease or transmission rates of the arbovirus in *Aedes aegypti*. One reason for that is scientific (i.e., it is tougher to prove over a longer time period), but part of it is regulatory. If you claim disease management, an INAD becomes a different ballgame and your hurdles increase exponentially. It may even be a different group at FDA who handles the application once disease is the identified target and it could become a human drug, not an INAD. Larissa or Brinda would be the ones to contact on that aspect.

John Kough has been more involved in the Wolbachia issues than I, so I am copying him on this so he can respond.

Hope this helps and I know John can fill you in further on our handling of Wolbachia infested mosquitoes as well as if Eliminate Dengue has contacted us.

Chris

From: Barbero, Robbie [mailto:Roberto_J_Barbero@ostp.eop.gov]
Sent: Friday, February 26, 2016 2:38 PM
To: Wozniak, Chris <wozniak.chris@epa.gov>
Subject: wolbachia and zika virus

Hi Chris,

Hope all is well. I'm working on Zika related items here at OSTP and am looking at some of the newer methods of controlling the spread of the virus.

I see that OPP received a request from University of Kentucky for an EUP for *Wolbachia pipientis* (w AlbB Strain) to determine its pesticidal value for suppression and elimination of *Aedes aegypti*, the mosquito that transmits Zika virus (though Zika is not named in the docket): >>><http://www.regulations.gov/@@@;#!documentDetail;D=EPA-HQ-OPP-2015-0374-0001>.

I also understand that the Eliminate Dengue team (<http://www.eliminatedengue.com/>) may have chatted with OPP in the past about whether OPP would have oversight responsibilities for the Eliminate Dengue team's strain of *Wolbachia*.

Do you know whether OPP would have oversight responsibilities for a trial to test the ability of the Eliminate Dengue *Wolbachia* strain to limit Zika spread?

I believe I remember you bringing up *Wolbachia* at some point in the past during our conversations, which is why I'm reaching out to you.

If you're not the right person to connect with on this, please let me know with whom I should connect.

Thanks much for your help!

Best,

Robbie Barbero, Ph.D.
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